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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/697,862

10/30/2003

Jason A. Demers

1062/D84

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73544

7590

06/19/2008

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/697,862	Applicant(s) DEMERS ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 49-60 and 67-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 and 61-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/29/04, 7/18/05, 12/15/05, 9/14/06, 5/10/07, 11/15/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Species C, claims 1-48, 61-66, and 69 with traverse in the reply filed on 20 March 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Upon further consideration, the Examiner is separately restricting claim 69 from Group I. Claim 69 specifically sets forth a spike with two fluid channels, wherein the other claims do not require the two channels. The inventions are related, but distinct, since a two-channel spike may allow for air venting or complex mixing operations that are not possible with a single-channel spike. Since the subject matter (the number of channels in the spike) is distinct, restriction for examination purposes is proper.
3. Claims 49-60 and 67-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

4. Claim 41 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant claims a

“plurality” of spikes in parent claim 25, then claims a “second” spike in claim 41. A plurality of spikes necessarily includes a second spike. As such, the claim fails to further limit the parent claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-8, 11, 15-18, 20-24, 25-32, 35, 39-41, 42, 44-47, 61, 62, 63, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al.

In the specification and figures, Kramer discloses the apparatus substantially as claimed by applicant.

With regard to claims 1, 2, 4, 5, 61, Kramer discloses a pump cassette 10 for use with a pump 42, wherein the cassette includes at least one pump chamber 44, and a first inlet port 22 (see FIGS 1-2 and accompanying text).

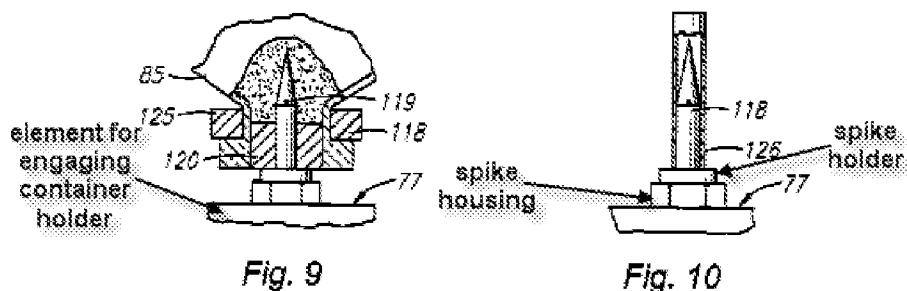
Kramer fails to disclose a mechanically driven spiking assembly, but does disclose that the cassette is connected to at least a first container C via tubing lines S. Bloom discloses an automated vial loading method and apparatus for administering medicament to a patient. The apparatus comprises a cassette and a mechanically operated spiking assembly (vial loading assembly 200) comprising a spike 118 that is in

fluid communication with the pump cassette (see Bloom column 19). The mechanically operated assembly prevents accidental needle sticks to the operator. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a mechanically driven spiking assembly as disclosed by Bloom to the apparatus disclosed by Kramer in order to prevent accidental needle spikes with manual loading, as taught by Bloom.

With regard to claim 3, Bloom discloses that the connections between the cassette and the vials may be used to both inject and withdraw fluid from the vials 85, meeting the limitations of the claims (see Bloom column 16, lines 54-67).

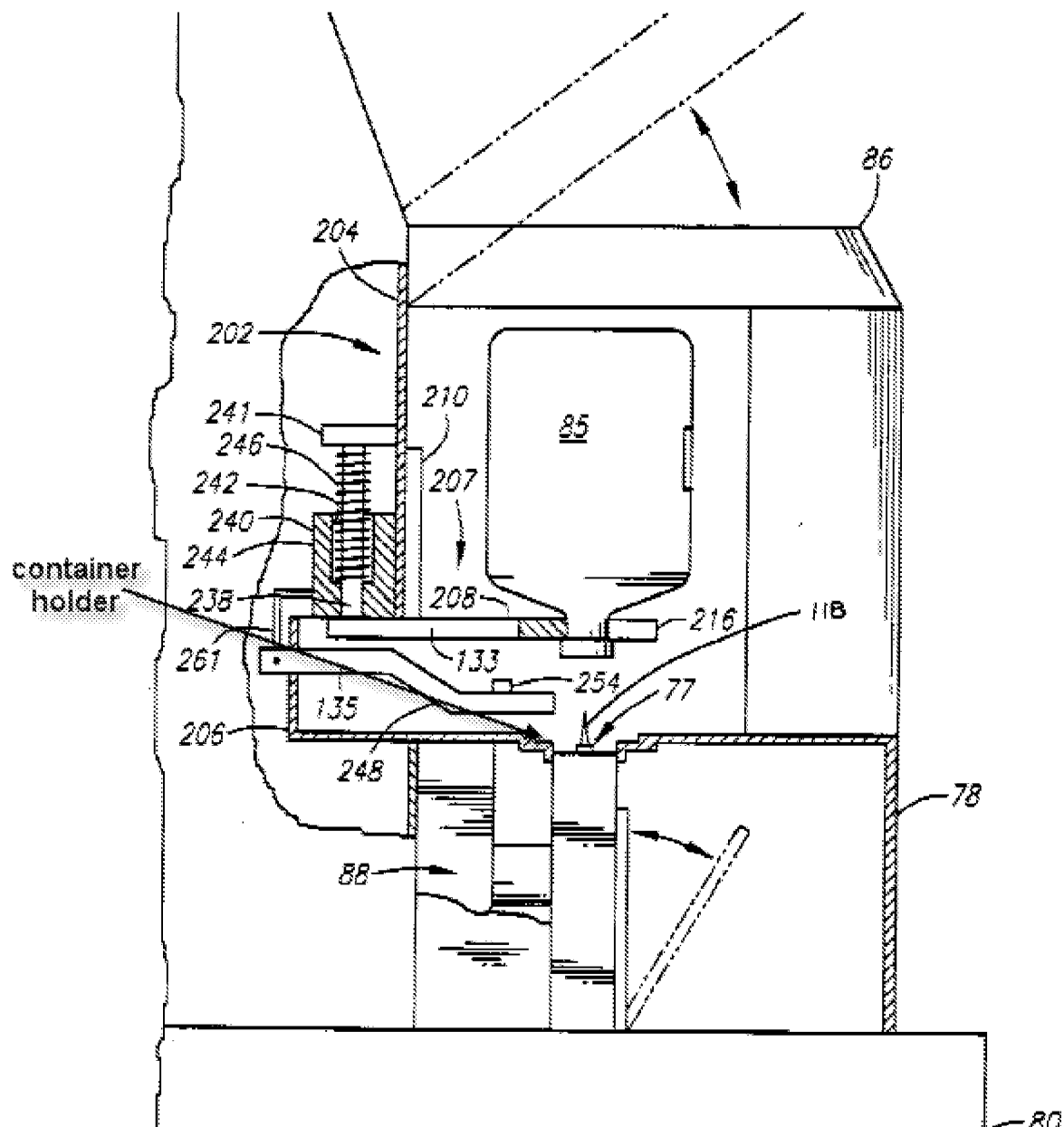
With regard to claims 5, 6, and 30, spike housing comprises two substantially identical ring halves that are joined together to form a ring.

With regard to claims 7, 31, Bloom illustrates that the spike assembly comprises a spike housing (unlabeled, see FIGS 10, 13).



With regard to claims 8, 32, Bloom teaches that the spike assembly comprises a spike holder, but is silent as to the method of attachment. The claimed phrase “wherein the spike holder is overmolded onto the at least one spike” is being treated as a product by process limitation; that is, that the spike holder is overmolded onto the spike. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113. Thus, even though Bloom is silent as to the process used to attach the spike holder, it appears that the product in Bloom would be the same or similar as that claimed; especially since both applicant’s product and the prior art product comprises a spike with a spike holder.

With regard to claims 15, 16, 39, 40 Bloom discloses that the housing 208 of the spike assembly comprises an element, top of cassette 77, that engages a container, surface 206. (See FIG 13, as annotated by the Examiner, below.)



With regard to claims 17, 18, 20-22, 25-29, 41, 42, 44-46, 62, 63, 65, 66, both Kramer and Bloom teach that the apparatus may comprise multiple spikes, containers, connecting tubing lines, and ports, suggesting the apparatus claimed by Applicant (see Kramer FIG 2, Bloom FIGS 5A, 8).

With regard to claims 23, 24, 47, 48 Bloom discloses that the cassette may comprise two fluid chambers 109, 110, that may be programmed to operate as claimed, wherein the cassette is pneumatically operated by pump 88 (see Bloom column 16, lines 47-53, column 15, lines 34-36).

With regard to claims 11 and 35, Bloom discloses that the apparatus may comprise a spike guard or cap 126 (see FIG 10 and accompanying text).

7. Claims 9, 10, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 4,111,469 to Kavick .

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 9, 10, 33, and 34, the cited prior art fails to teach a barb on the tubing holder to retain a tube in place and an element on the housing to retain the tube in place. However, Kavick discloses a device for connecting fluid conduits with a pointed stem connected to a holder 23, inside a housing 16, wherein the holder and stem comprise barbs 26 and the housing comprises spikes 12 to retain an inserted tube 21 in place. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add retaining means to a housing and a holder as taught by Kavick, in the assembly suggested by the cited prior art, in order to sandwich a tubing member between retaining elements to secure it in place.

8. Claims 12-14, 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 6,159,192 to Fowles et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 12, 13, 36, and 37, the cited prior art fails to teach a spike guard with a grommet capable of being pierced by the spike wherein the grommet may function as a fluid seal when in contact with a container. Fowles teaches a medical connector apparatus comprising a spike 37, spike guard 106 with a pierceable membrane or grommet at the end of the guard 106 (see FIG 4). When engaged with a container, the grommet may scrunch up and seal against the spike housing, creating a fluid seal (see FIG 3).

With regard to claims 14 and 38, the spike assembly disclosed by Fowles comprises sleeves that protect the spike from inadvertent needle operator intrusion, wherein the sleeves have locking ribs that may be engaged to lock the sleeves in a particular position, and then disengaged to move the sleeves to another position (see column 7, lines 25-46). Accordingly, it is the position of the Examiner that the locking mechanism claimed by applicant is suggested in the prior art. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the fluid mixing and injection assembly with spike as suggested by the cited prior art with a spike guard with tabs as disclosed by Fowles, to enable the guard to be moved from a protecting position to an engaged position, as taught by Fowles.

9. Claims 19, 43, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,062,774 to Kramer et al in view of US 6,070,761 to Bloom et al, further in view of US 5,116,316 to Sertic et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 19, 43, and 64, the cited prior art fails to teach a filter within a flow path. Seric teaches an automatic in-line reconstitution and delivery system comprising a filter 81 between vial 42 and the delivery system (see column 9, lines 40-48) in order to prevent particulate matter from being administered to the patient. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to add a filter as disclosed by Sertic to the cassette and spiking assembly suggested by the cited prior art in order to prevent undissolved particulate matter from being administered to the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
12 June 08